510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K111509

A. Submitter SweetSpot Diabetes Care, Inc.
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Email: chris@sweetspotdiabetes.com

Date Prepared: September 28, 2011

B. Device Names

Classification names
1) System, Test, Blood Glucose, Over the Counter, Class II at 862.1345, NBW
2) Calculator/data processing module for clinical use, Class I at 862.2100, JQP

Common/usual names
1) Blood glucose meter
2) Data management software

Proprietary names
1) Various, from various manufacturers
2) SweetSpot Diabetes Data Management Service

C. Predicate Device

MyCareTeam-Diabetes, K073699, NBW/JQP

D. Device Description

The SweetSpot Service allows patients or healthcare professionals to download data from blood glucose meters (BGM) and generates a report from the downloaded data, which is delivered to the healthcare professional for use in patient management. The Service is comprised of three different types of data retrieval stations, a Fetch Utility, a data processing and storage platform, report generation software, and an information delivery service.

The first type of data retrieval station is a Front-Office Kiosk – a dedicated off-the-shelf computer that a patient uses to download the data from their device or devices (if they download from multiple devices the Service will consolidate that data into a single report). A device-specific cable is required to connect the BGM to the Kiosk for data download. Once the data is downloaded, it is processed into a report and delivered according to the specific clinic's needs and workflow.

The second type of data retrieval station is a Back-Office Kiosk – a dedicated off-the-shelf computer that healthcare professionals use to download patient devices and/or monitor reports. This kiosk is also configured for the workflow needs of the clinic.

The third type of data retrieval station is a Back-Office Web Application – a standalone application used by healthcare professionals that does not require a dedicated computer. Each customer uses a specific instance of the web application through a unique URL. This launches a proprietary web application configured for that specific clinic's needs and workflows.

The SweetSpot Fetch Utility retrieves data from various BGM manufacturers' devices and includes device drivers for multiple manufacturers. The Fetch Utility is centrally updated and maintained. When any version of the SweetSpot Services retrieval stations – in any setting – is directed to perform data retrieval, the Service ensures the most up-to-date version of the Fetch Utility is used.

The SweetSpot Service is primarily web-based and is delivered using a software-as-a-service (SaaS) model. All data storage and processing takes place on remotely hosted virtualized computing resources on the Internet, often referred to as "cloud computing".

E. Intended Use

The SweetSpot Diabetes Data Management Service is intended for use in in clinical settings by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical blood glucose test results to support effective diabetes management. It is intended for use as an accessory to blood glucose meters with data interface capabilities.

F. Comparison with the Predicate Device

The SweetSpot Service is substantially equivalent to the MyCareTeam (MCT-Diabetes product), K073699. Both devices are intended to provide access to BGM data to assist in the monitoring of an individual's blood glucose levels. Both devices are designed for use by patients and by healthcare professionals. Both devices support the most commonly used blood glucose meters. The SweetSpot Service has the same technological characteristics as the predicate device with minor exceptions (e.g., the predicate device operates only on PC operating systems while the SweetSpot Service operates on both PC and Mac OS; report contents and data presentation are slightly different), but the exceptions do not affect safety or effectiveness. Any differences in technology have been addressed by software validation and verification testing, and usability testing (conducted in accordance with ISO15197: 2003).

G. Nonclinical Data

Software verification and validation testing showed that the SweetSpot Service performs as designed.

H. Clinical Data – User Evaluations

A lay user evaluation was performed by typical outpatients at two different typical sites of use. A total of 88 respondents completed a user survey after using the SweetSpot Front-Office Kiosk. On a scale of 1 to 5, with 1 being "Strongly Disagree" and 5 being "Strongly Agree", 98% of the users thought that the SweetSpot Service was easy to use (4.9 average rating at both evaluation sites), and 90% thought that they would be more likely to bring their meters to appointments in the future if the SweetSpot Service was available (ratings of 4.6 and 4.5, respectively, at the user evaluation sites). Meter download success rates were 97.6% and 95.3%, respectively (96.5% overall success rate).

A separate user evaluation of the Back-Office Kiosk was performed by healthcare professionals (HCP) at one typical site of use. A total of 11 respondents completed a user survey after using the SweetSpot Back-Office Kiosk as part of a larger research study. The HCP preferred the consistency, simplicity/ease of use, and speed of the SweetSpot download process to their previous various meter-specific processes, and also preferred the consistency of having one report format for all patients vs. their previous different meter-specific report formats. The HCP thought that these features would improve workflow, decrease meter download time, simplify decision-making, reduce training time, and reduce the chance for mistakes in data management.

The accuracy of the Fetch process in lay users' hands was evaluated at a typical site of use, where lay users used the Front-Office Kiosk to download data from their BGM, and a SweetSpot employee used the BGM manufacturer's download software to download data from the same BGM. The two download files were compared, and there was 100% agreement between the download files, demonstrating that the lay user does not introduce error into the download process when using the Front-Office Kiosk and the SweetSpot Fetch process.

I. Conclusions Drawn from Testing

Software verification and validation testing and user evaluations showed that the SweetSpot Service performs as designed and meets the users' needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SweetSpot Diabetes Care, Inc.
c/o Chris Logan
CEO
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Portland, OR 97213-1924

NOV - 9 2011

Re: k111509
Trade/Device Name: SweetSpot Diabetes Data Management Service
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: September 30, 2011
Received: October 3, 2011

Dear Mr. Logan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K111509

Device Name: SweetSpot Diabetes Data Management Service

Indications for Use:

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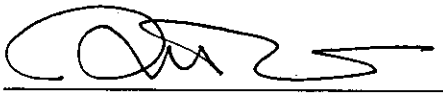
Prescription Use __X_____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K111509